510(k) Summary

Date Prepared: December 9, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Air Barrier System (ABS).

1. Company making the submission:

Owner/Submitter: Nimbic Systems, Inc.
4910 Wright Road, Suite 170
Stafford, Texas 77477

Contact Person: Sean Self
President
281-565-5715
281-565-5712 fax
self@nimbicsystems.com

2. Device Name and Classification:

Common/Usual Name	:	**Air-handing apparatus for a surgical operation room**
Proprietary Name	:	**Air Barrier System (ABS)**
Device Class	:	**Class II**
Regulation Number	:	**21 CFR 878.5070**
Product Code	:	**ORC**
510(k) Number	:	**K123006**

3. Predicate Device

This submission for the Air Barrier System (ABS) Model 5001 is for new claims only. The Air Barrier System (ABS) Model 5001 specifications are the same as the model 1001 released to market [K092801]. The Air Barrier System (ABS) Model 1001 is the primarily predicate device.

4. Intended Use Statement

The Air Barrier System is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty and posterior vertebral fusion and laminoplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical surface with no gap between the bottom of the

nozzle and the surface, (2) the incision plane is parallel with the direction of air flow, and (3) the incision dimensions are within: 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area.

5. Description of Device

The ABS device controls the airborne surgical environment at a specific and limited location adjacent to and over surgical incisions by emitting a non-turbulent flow of HEPA filtered air that displaces the presence of airborne colony-forming units and particulate matter within surgical site dimensions of 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable outside of these dimensions and effectiveness depreciates beyond this specified area.

Clinical studies at two sites by different investigators have been conducted to demonstrate the performance characteristics of the Air Barrier System (ABS) during surgical procedures:

In the first study, twenty-nine (29) patients were randomized into one of three groups: with the ABS active (experiment), with the ABS present but not active (sham), and with no ABS device present (control). Airborne particulate and microorganism samples were collected simultaneously at a discrete single location at the surgical incision within the ABS area of effect and from a discrete single location within the sterile field, but not within the ABS area of effect. The airborne particulate and microorganism counts observed in the experiment group were significantly lower ($P<0.001$) than that observed in the sham and control groups. In the experiment group, the mean microorganism density at the sampling location within the ABS area of effect was 1.60 colony-forming units per cubic meter compared to 10.73 at the location outside the ABS area of effect. For particulate of size ≥5µm, the mean observed particulate density in the experiment group was 524 particles per cubic foot compared with 3853 and 4092 particles per cubic foot in the sham and control groups, respectively.

In the second study, thirty-eight (38) patients undergoing instrumented posterior vertebral fusion or laminoplasty were randomized into one of two groups: with the ABS device (experiment) and with no ABS device (control). Airborne particulate and microorganism samples were collected simultaneously at a discrete single location at the surgical incision in both groups at ten-minute intervals for the first 100 minutes of the procedures. The airborne particulate and microorganism counts observed in the experiment group were significantly lower ($P<0.001$) than that observed in the control group. The mean experiment group microorganism density at the sampling location within the ABS area of effect was 1.55 colony-forming units per cubic meter compared to 5.05 in the control group. The mean experiment group density of particles sized ≥5µm at the sampling location within the ABS area of effect was 1325 particles per cubic foot compared to 4837 measured in the control group.

The Air Barrier System (ABS) has two components: a Filter/Blower and an Air Delivery System.

The ABS Filter/Blower filters ambient air found in a typical surgical operating room through a High Efficiency Particle Arresting (HEPA) filter. The HEPA filtered air exits the Filter/Blower from an exit port on the top of the unit. The Filter/Blower is non-sterile and reusable.

The Air Delivery System, consisting of an Air Supply Hose and Nozzle, is sterile, single-use. The Nozzle portion is applied to the surgery site, on top of the incision drape and adjacent to a surgical incision. The end of the Air Supply Hose is plugged into the Filter/Blower's air exit port. HEPA filtered air then flows through the Air Supply Hose through the Nozzle and directly to the incision site.

6. Summary of the technological characteristics of the device compared to predicate device

The difference from the predicate Air Barrier System (ABS) Model 1001 [K092801], is new and extended claims of application to posterior vertebral fusion and laminoplasty procedures that are in covenant with Indications for Use statement.

The technology, design and method of construction of the Air Barrier System (ABS) Model 5001 are identical to the Air Barrier System (ABS) Model 1001, predicate device.

Comparison table of characteristics between current submission and predicate:

Parameter	This submission [K123006] Nimbic Systems' Air Barrier System with new claims	*Predicate* [K092801] Nimbic Systems Air Barrier System
Product Code	ORC	ORC
Regulation No.	878.5070	878.5070
Review Panel	General Hospital	General Hospital
Indications for Use	The Air Barrier System is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty and posterior vertebral fusion and laminoplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical	The Air Barrier System (ABS) is indicated as a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow form the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical surface with no gap between the bottom of the nozzle and

Parameter	This submission [K123006] Nimbic Systems' Air Barrier System with new claims	*Predicate* [K092801] Nimbic Systems Air Barrier System
	surface with no gap between the bottom of the nozzle and the surface, (2) the incision plane is parallel with the direction of air flow, and (3) the incision dimensions are within: 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area.	the surface, (2) the incision plane is parallel with the direction of air flow, and (3) the incision dimensions are within: 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area. Patient age restrictions: none.
Physical		
Housing Dimensions	11 X 11 X 25 inches	11 X 11 X 25 inches
Weight in pounds	48	48
Material type	Stainless Steel	Stainless Steel
Filter/Blower Output (CFM)	150	150
Blower Recertification Interval	Annual	Annual
Electrical		
Voltage (VAC)	120	120
Frequency (Hertz)	60	60
Max Current (Amps)	5	5
HEPA Filtration Specifications		
Filtration Efficiency	99.97% @ 0.3 micron	99.97% @ 0.3 micron
HEPA Filter Media	Continuous pleated glass microfiber	Continuous pleated glass microfiber
Air Inlet Pre-Filter Media	Polyurethane Foam	Polyurethane Foam
Measured average particulate density @ surgical incision (0.5 µm particles per cubic foot)	68,122	29,992

Parameter	This submission [K123006] Nimbic Systems' Air Barrier System with new claims.	*Predicate* [K092801] Nimbic Systems Air Barrier System
CFU's @ Surgical Incision (Colony Forming Units/m^3)	1.57	1.60
Air Volume Delivered to incision in CFM	41	41
Hose and Nozzle Specifications		
Sterility	Sterile	Sterile
Use	Single-Use	Single-Use
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL
Sterilization Method	ETO	ETO

7. Testing

The Air Barrier System (ABS) Model 5001 physical and operational specifications are identical to Air Barrier System (ABS) Model 1001 [K092801]. No changes have been made to the design or method of construction between Models 5001 and 1001.

The Electrical Safety and Electromagnetic Compatibility testing results are identical to Air Barrier System (ABS) Model 1001 [K092801]. For completeness the testing documentation is presented in this submission in the appropriate Sections.

Bench Testing – The bench performance testing submitted in this submission is identical to that submitted in the predicate submission [K092801]. Specifically, it includes two feasibility studies (Ambient and Challenge Tests), and the final bench testing reports (Validation and Performance Qualification). The Validation and Performance Qualification test results demonstrate that the ABS successfully met the criteria for achieving reduction of airborne contamination at the simulated incision site and over the specified control area.

Clinical Testing – Clinical testing was provided in the previous submission [K092801] demonstrating clinical performance of the ABS during hip surgery. Additional clinical data is provided in this submission demonstrating clinical performance of the ABS during posterior cervical and lumbar fusion procedures at the Michael E. DeBakey VA Medical Center (MEDVAMC). The goal of this submission is to incorporate these additional procedures into the ABS' indications for use.

The objective of the MEDVAMC study was to determine the degree to which the Air Barrier System (ABS), which deploys directed HEPA air flow across the surgical field, reduces airborne particulate and airborne colony forming units (e.g., bacteria and fungal spores) at surgical incisions during posterior instrumented lumbar and cervical vertebral fusion procedures. This was a prospective randomized trial with one control

group and one experiment group with an enrollment of up to 40 patients (41 patients actually enrolled). Statistically valid conclusions were able to be made regarding the ABS intended use after analyzing 38 surgery cases.

The clinical trial results demonstrated a statistically significant reduction ($p \leq 0.0001$, $\alpha=0.05$) of both CFU and particulate sized ≥5µm in the ABS group versus control group. CFU were reduced from a mean of 5.05 to 1.55 CFU/m^3. Particulate sized ≥5µm were reduced from a mean of 4837 to 1325 particles/m^3.

8. Conclusion

The results of all of the tests performed, including clinical and nonclinical tests, demonstrate that the ABS-5001 is as safe, and as effective as the predicate device.

9. Rx or OTC

The Air Barrier System (ABS) Model 5001 is a Rx Prescription device per 21 CFR Subpart D. The indication for use is for clinical settings only as stated in device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Nimbic Systems, Incorporated
C/O Mr. Harvey Knauss
Contract Consultant
DELPHI Consulting Group
11874 South Evelyn Circle
HOUSTON TX 77477

Re: K123006
Trade/Device Name: Air Barrier System
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-handling Apparatus For A Surgical Operating Room
Regulatory Class: II
Product Code: ORC
Dated: November 26, 213
Received: December 17, 2013

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

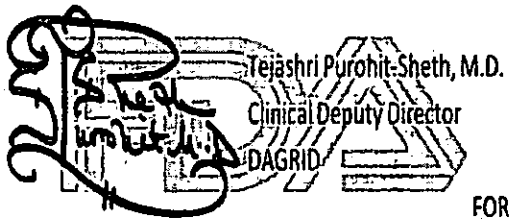
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123006

Device Name: **Air Barrier System (ABS)**

The Air Barrier System is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty and posterior vertebral fusion and laminoplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical surface with no gap between the bottom of the nozzle and the surface, (2) the incision plane is parallel with the direction of air flow, and (3) the incision dimensions are within: 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area.

Prescription Use **YES** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S
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